

Amendments to the Claims:

Following is a complete listing of the claims pending in the application, as amended:

1-17. Cancelled

18. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;
applying an aqueous solution of the pharmacologically active agent onto the member;
and

drying said applied aqueous solution to form a dry agent-containing coating on said member;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25 °C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25 °C of less than about 500 centipoises.

19. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;
applying an aqueous solution of the pharmacologically active agent onto only one or more of said microprotrusions; and

drying said applied aqueous solution to form a dry agent-containing coating only on one or more of said microprotrusions;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25 °C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25 °C of less than about 500 centipoises.

20. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions; said microprotrusions adapted to pierce through the stratum corneum to a depth of less than about 500 micrometers;

applying an aqueous solution of the pharmacologically active agent onto the member; and

drying said applied aqueous solution to form a dry agent-containing coating on said member;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25 °C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25 °C of less than about 500 centipoises.

21. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions; applying an aqueous solution of the pharmacologically active agent onto the member; and

drying said applied aqueous solution to form a dry agent-containing coating on said member, said coating having a thickness [being] less than a thickness of the microprotrusions.

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25 °C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25 °C of less than about 500 centipoises.

22. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions, said microprotrusions having a length of less than 500 micrometers and a thickness of less than 25 micrometers;

applying an aqueous solution of the pharmacologically active agent onto the member; and

drying said applied aqueous solution to form a dry agent-containing coating on said member;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25 °C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25 °C of less than about 500 centipoises.

23. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;
applying an aqueous solution of the pharmacologically active agent onto the member;
said pharmacologically active agent selected from the group consisting of adrenocorticotrophic hormone (ACTH (1-24)), calcitonin, desmopressin, leutinizing hormone releasing hormone (LHRH), goserelin, leuprolide, buserelin, triptorelin, ~~other LHRH analogs~~, parathyroid hormone (PTH), vasopressin, deamino [Val4, D-Arg8] arginine vasopressin, interferon alpha, interferon beta, interferon gamma, follicle stimulating hormone (FSH), erythropoietin (EPO), granulocyte macrophage colony stimulating factor (GM-CSF), granulocyte colony stimulating factor (G-CSF), interleukin-10 (IL-10), glucagon, growth regulatory factor (GRF), analogs thereof, and pharmaceutically acceptable salts thereof; and

drying said applied aqueous solution to form a dry agent-containing coating on said member;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25 °C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25 °C of less than about 500 centipoises.

24. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;
applying an aqueous solution of the pharmacologically active agent desmopressin onto the member; and

drying said applied aqueous solution to form a dry agent-containing coating on said member;

wherein said agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at

about 25 °C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25 °C of less than about 500 centipoises.

25-27. (Canceled).

28. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;
applying an aqueous solution of the pharmacologically active agent onto the member in a non-contiguous pattern; and

drying said applied aqueous solution to form a dry agent-containing non-contiguous coating on said member;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25 °C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25 °C of less than about 500 centipoises.

29. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;
applying an aqueous solution of the pharmacologically active agent onto the member;
~~said pharmacologically active agent being sufficiently potent to be therapeutically effective when administered in an amount less than about 0.25 milligrams and~~

drying said applied aqueous solution to form a dry agent-containing coating on said member;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about ~~[[1]]~~ 0.25 mg, said agent having an aqueous solubility at about 25 °C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25 °C of less than about 500 centipoises.

30. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;

applying an aqueous solution of the pharmacologically active agent onto the member;
and

drying said applied aqueous solution to form a dry agent-containing coating on said member;

wherein said agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25 °C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25 °C of less than about 50 centipoises.

31. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;
applying an aqueous solution of the pharmacologically active agent onto the member;
and

drying said applied aqueous solution to form a dry agent-containing coating on said member; said coating having a thickness over a surface of said member of less than 50 micrometers;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25 °C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25 °C of less than about 500 centipoises.

32. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;
applying an aqueous solution of the pharmacologically active agent onto the member;
and

drying said applied aqueous solution to form a dry agent-containing coating on said member; said coating having a thickness over a surface of said member of less than 25 micrometers;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25 °C

of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25 °C of less than about 500 centipoises.

33. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;
providing an aqueous solution comprising said pharmacologically active agent and an adjuvant;

applying said aqueous solution onto the member; and
drying said applied aqueous solution to form a dry agent-containing and adjuvant-containing coating on said member;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25 °C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25 °C of less than about 500 centipoises.

34. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;
applying an aqueous solution of the pharmacologically active agent onto the member;
and

drying said applied aqueous solution to form a dry agent-containing coating on said member; said coating comprising a loading of said pharmacologically active agent of less than 1 mg/cm² of area of said member;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25 °C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25 °C of less than about 500 centipoises.

35. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;

applying an aqueous solution of the pharmacologically active agent onto the member;
and

drying said applied aqueous solution to form a dry agent-containing coating on said member; said coating comprising a loading of said pharmacologically active agent of less than 0.5 mg/cm² of area of said member;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25 °C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25 °C of less than about 500 centipoises.

36-46. (Canceled).

47. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;
applying an aqueous solution of the pharmacologically active agent onto said member by dip coating said member in said solution; and

drying said applied aqueous solution to form a dry agent-containing coating on said member;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25 °C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25 °C of less than about 500 centipoises.

48-50. Cancelled